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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,431	03/25/2005	Gregoire Prevost	117P/PCT2/US	6671

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EXAMINER

OLSON, ERIC

ART UNIT	PAPER NUMBER
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1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,431	Applicant(s) PREVOST ET AL.	
	Examiner ERIC S. OLSON	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's communication submitted September 16, 2009 wherein claims 22, 26, 31, and 32 are cancelled. This application is a national stage application of PCT/IB03/04922, filed September 29, 2003, which claims benefit of provisional application 60/414103, filed September 27, 2002.

Claim 17 is pending in this application.

Claim 17 as amended is examined on the merits herein.

Applicant's amendment, submitted September 16, 2009, with respect to the rejection of instant claims 22, 26, 31, and 32 under 35 USC 103(a) for being obvious over Gordon in view of Rybak in view of Porter et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been rejected.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1623

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (PCT international publication WO00/39130, of record in the previous office action) in view of Rybak. (PCT international publication WO01/64197, of record in the previous office action)

Gordon et al. discloses a pharmaceutical composition comprising one of a variety of compounds having an identical formula to formula (I) recited in instant claim 2. (pp. 2-9) Further specifically recited embodiments include the farnesyl transferase inhibitors of instant claim 17. (pp. 17-27) These compounds are disclosed to possess anti-tumor activity (p. 16, lines 16-29) and to be useful for inhibiting prenyl transferases including farnesyl transferase. (p. 9, lines 8-25) Gordon et al. does not disclose a pharmaceutical composition comprising a combination of compound according to structure (I) and an anthracycline, or a method of treating nasopharyngeal cancer by administering such a composition to a subject. Gordon et al. also does not disclose a pharmaceutical kit comprising such a composition according to instant claims 34 and 38.

Rybak discloses therapeutic combinations of anthracyclines and farnesyl transferase inhibitors which are effective in the inhibition of tumor cell growth. (p. 13, lines 3-6) Preferred anthracycline derivatives include daunorubicin, doxorubicin, and idarubicin. (p. 21, lines 24-26) These compositions may be used in a method of inhibiting abnormal cell growth or treating various cancers having aberrant or mutated *ras* oncogene, (p. 22, lines 12-38) in a mammal, particularly a human. The two components may be administered either simultaneously or sequentially. (p. 23, lines 16-18)

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a pharmaceutical composition comprising a farnesyl transferase inhibitor according to Gordon et al. and further comprising an anthracycline such as doxorubicin. One of ordinary skill in the art would have been motivated to combine the two components and to administer them to a patient suffering from cancer because both components were known to be useful for the treatment of cancer. One of ordinary skill in the art would have reasonably expected success because both compounds were known to be useful for the same purpose. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted February 23, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the sheer number of disclosed farnesyl transferase inhibitors in the prior art means that one of ordinary skill in the art would be unable to pick out one particular compound to use in the claimed invention. In particular, Applicant argues that although only 40 specific compounds were synthesized, Gordon still prophetically discloses a vast number of possible compounds, namely any compound falling within the scope of the generic structure disclosed on pp. 2-8 of Gordon, and these prophetic compounds would prevent one of ordinary skill in the art from being able to select one particular compound to use in the invention. Firstly, the so-called prophetic examples have not been synthesized or tested, and are not even specifically disclosed. Their existence is merely inferred from the fact that they fall within the scope of a generic structure pictured by Gordon. In contrast to this vague disclosure of possible compounds, the 40 actual synthesized compounds have the clear advantage of having already been synthesized by known procedures and specifically put forward by Gordon as workable solutions to the problem being solved by the reference. Far from being mentioned "in passing" as asserted by the Applicant, these 40 compounds are pointed to as the conclusion of the invention of Gordon and would thus be recognized as specifically preferred embodiments by one of ordinary skill in the art. By contrast, it is the thousands of putative compounds that Applicant asserts to be disclosed by the generic structure on pp. 2-8 of Gordon that are

mentioned in passing, and which would have thus been passed over by one of ordinary skill in the art in favor of the 40 clearly disclosed compounds.

Furthermore, the mere fact that the prior art discloses a large number of solutions to a problem does not therefore render any individual solution nonobvious merely because one of ordinary skill in the art would supposedly be unable to decide on a particular solution from among those available. Rather, in a well-developed art such as cancer chemotherapy, those of ordinary skill in the art are aware that thousands of different therapeutic agents are known and, far from being bewildered by the number of choices available, they are able, as part of the ordinary skill in the art, to choose the appropriate therapeutic agent out of the broad number available.

Finally, regarding Applicant's reliance on Takeda to show that one of ordinary skill in the art could not have selected the claimed compound from a broad selection in the prior art, it is reiterated that Takeda dealt with a circumstance much different than the present case. The compound at issue in Takeda was (a) never specifically disclosed in the prior art, and (b) based on a lead compound that the prior art identified as inferior to other potential lead compounds. By contrast, Gordon specifically points out the claimed compound as one of a discrete number of preferred compounds. By the reasoning of Takeda, one of ordinary skill in the art would have selected one of the 40 preferred compounds of Gordon and used it without further modification, just as is asserted in the above ground of rejection, rather than randomly modifying these compounds to arrive at the hypothetical compounds contained within the broad generic structure disclosed by Gordon.

For these reasons the rejection is deemed proper and made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 and 13 of copending Application No. 12/073729. (Published as pre-grant publication 2008/0161253, cited in PTO-892, herein referred to as ‘729) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 11 and 13 of ‘729 anticipate the claimed invention.

Claim 11 of ‘729 discloses a pharmaceutical composition comprising the specific compound recited in instant claim 17 and an anthracycline. Claim 13 claims a

Art Unit: 1623

composition wherein the anthracycline is doxorubicin. Therefore claims 11 and 13 of '729 anticipate the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument: Applicant has not addressed the above ground of rejection. Therefore the rejection is maintained and made **FINAL**.

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
12/29/2009

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623